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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/435,274	11/05/1999	VITALY H. CITOVSKY	001.00301	4987

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EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 01/14/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/435,274

Applicant(s)

CITOVSKY ET AL.

Examiner

David A Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 and 35 is/are rejected.
- 7) ☒ Claim(s) 34, 36 and 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 October 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Actions, filed on February 26, 2002 as Paper No. 17 (concerning a response to a Non-final Office Action) and on October 28, 2002 as Paper No. 21 (concerning a response to a Letter of Non-responsiveness). Amendments were made to the claims. In addition, claims 38-78 were cancelled without prejudice.

Claims 1-37 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, Paper No. 15, mailed August 13, 2001, that is not addressed in this action has been withdrawn.

This Office Action contains no new rejections, and is therefore made FINAL.

Drawings

The corrected or substitute drawings were received on October 28, 2002 as Paper No. 21. These drawings are accepted by the Draftsperson.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-33 and 35 are rejected under 35 U.S.C. 102(a) as being anticipated by Ueki *et al.* (WO 98/49284). **This rejection is maintained with respect to the indicated claims for reasons made of record in the Office Action mailed August 13, 2001.**

Response to Arguments Concerning Claim Rejections Under 35 USC § 102

Applicant's arguments filed February 26, 2002 in Paper No. 17 have been fully considered but they are not persuasive. Applicants arguments comprise the following points: (1) that the prior art reference merely states that the DNA that is transferred into the host include DNA encoding a transcription factor from which the nuclear transportability has been eliminated; and (2) that the prior art reference, Ueki *et al.* does not disclose that all of the elements of the fusion protein, other than the protein of interest, have no nuclear localization signals.

These arguments are not persuasive for the following reasons:

1. It appears that applicant is arguing that a nuclear localization signal does not pertain to nuclear transportability, and *vice versa*. Firstly, applicant is reminded that the document provided as prior art is a literal translation from Japanese into English, and that there may not be a good transition for the term "nuclear localization signal". Secondly, it is clear that the nuclear transportability that is referred to in Ueki *et al.* regards nuclear localization because the fusion protein that is being taught is a transcription factor, and transcription occurs inside the nucleus. Therefore the specification of Ueki *et al.* is to be interpreted where "nuclear transportability" and "nuclear localization signal" are interchangeable.

2. It is clear from the specification of Ueki *et al.*, for example on pages 3-4 (third full paragraph) of the translation, that they are describing a fusion protein having both a DNA binding domain and a transcriptional activation domain, where the nuclear transportability region (e.g., a nuclear

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localization signal) has been removed from the transcription factor (indicating the whole transcription factor fusion protein), thereby inhibiting its translocation into the nucleus. As a result, the transcription factor *must not* contain a nuclear localization signal. Ueki *et al.* further discloses fusing test DNA to the transcription factor lacking the “nuclear localization signal” as a means of testing the ability of that test DNA to serve as a “nuclear localization signal”, by testing the activation of transcription of a detectable marker gene (e.g., lacZ) by the transcription factor fusion protein (see for example pages 4-5 of the translation). As it was already established that the transcription factor fusion protein must not contain a nuclear localization signal, the only source to provide such a nuclear localization signal must be the test DNA. In combination with statements made in section 1 of this response, this establishes that Ueki *et al.* indeed teaches all of the elements of the claimed invention.

In conclusion, it is found that Ueki *et al.* discloses all of the features of the claimed invention, briefly a method of identifying nuclear localization signals by fusing a test DNA sequence to a transcription factor fusion protein that has been disabled for its ability to localize to the nucleus, and measuring the transcription of a marker gene under the control of the transcription factor fusion protein, as well as the corresponding nucleotides, vectors, fusion proteins and host cells.

Allowable Subject Matter

Claims 34, 36 and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

As no new rejections have been raised in the Office Action, this Office Action is made FINAL.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Lambertson
January 6, 2003

DAVID GUZO
PRIMARY EXAMINER
